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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,347	03/06/2006	Jukka T Salonen	0933-0241PUS1	7762

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
03/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/530,347	SALONEN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-20 (in part), drawn to methods for diagnosing susceptibility to cardiovascular disease by assaying for a genetic variation or polymorphism.

Group II, claims 21-23 (in part), drawn to kits comprising means for detecting a genetic variation or a polymorphism.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the claimed inventions do not share a linking technical feature because the technical feature of invention II was known in the art at the time the invention was made. For example, Mullis (U.S. Patent No. 4,683,195; col. 3, lines 34-55) teaches kits for detecting a mutation in a target nucleic acid comprising reagents for performing amplification of a target nucleic acid and reagents for performing hybridization to detect a mutation in an

amplified target nucleic acid. In particular, the kit includes the reagents of a polymerizing agent and nucleoside triphosphates, and a means for detecting hybridization between an amplified target nucleic acid and a probe. Accordingly, the reagents present in the kit of Mullis have the property of being a means for detecting a genetic variation (i.e., mutation) in 3 or more of the genes recited in claim 21. Note that the recitation of "for diagnosing a susceptibility to a cardiovascular disease" merely sets forth the intended use or purpose of the claimed kits, but does not limit the scope of the claims with respect to the novelty or obviousness of the kits. Accordingly, claims 21-23 are considered to encompass any kit comprising a means for detecting a genetic variation or polymorphism in three of the recited genes. Regarding claim 22, the reagents in the kit of Mullis can be used for real-time PCR based tests. Regarding claim 23, with respect to the "questionnaire," it is noted that the written material in the questionnaire is not considered to be within the statutory classes and does not carry patentable weight (see MPEP 706.03(a)). Accordingly, the kits of claim 23 are considered to contain any written document. In view of the conventionality in the analytical arts of including instructions in kits, it would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made to have included instructions in the kit for the advantage of providing the practioner with information as to how to use the components of the kit. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

3. **Further restriction requirement applicable to invention I and II**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are the distinct combinations of three or more of the following genes:

(a) alpha2B-adrenoceptor

(b) apolipoprotein B

(c) dimethylarginine dimethylaminohydrolase 1

(d) fibrinogen-beta

(e) neuropeptide Y

(f) natriuretic peptide precursor A

(g) cystathione beta synthase

(h) glycoprotein IIb/IIIa

(i) lipoprotein lipase

For example, species I is the combination of the 3 genes of alpha2B-adrenoceptor, apolipoprotein B and dimethylarginine dimethylaminohydrolase I; species II is the combination of the three genes of alpha2B-adrenoceptor, apolipoprotein B and fibrinogen-beta; species III is the combination of the three genes of alpha2B-adrenoceptor, apolipoprotein B and neuropeptide Y, etc.

Applicant is required, in reply to this action, to elect a single species (i.e., a combination of 3 particular genes OR a combination of 4 particular genes, OR a combination of 5 particular genes etc) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

With respect to invention I, claims 1-20 read on the recited species.

With respect to invention II, claims 21-23 read on the recited species.

The following claim(s) are generic: None

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited genes differ from one another with respect to their nucleotide structure and the proteins that they encode. The genes thereby have a different chemical structure and different biological activity. Thus, the claimed genes do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

4. **Further restriction requirement applicable to invention I**

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

I. The combination of the mutations of Val32Met of natriuretic peptide precursor A, an insertion/deletion of three glutamic acids in the region of 12 Glu amino acids in the codons 298-309 of alpha2B-adrenoceptor, Thr98Ile of apolipoprotein B and SNP IVS2-33C>T of dimethylarginine dimethylaminohydrolase 1.

II. The combination of the mutations of 455G>A of fibrinogen-beta, an insertion or deletion of three glutamic acids in the region of 12 Glu amino acids in the codons 298-309 of a2B-adrenoceptor, and SNP -52C>G of neuropeptide Y.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The above election must be commensurate with the election as set forth in paragraph 4 above. For example, if Applicant elects the combination of genes of alpha2B-adrenoceptor, apolipoprotein B and dimethylarginine dimethylaminohydrolase I, then claims 13 and 14 will be withdrawn from consideration as being drawn to a non-elected invention. However, if additional claims are presented reciting alternative mutations, an election must be made regarding the particular combination of mutations that read on the elected combination of genes.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 13 encompasses species I.
Claim 14 encompasses species II.

The following claim(s) are generic: claims 1-12, and 15-20.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the recited chemotherapeutic drugs differ with respect to their chemical structure and with respect to their functional and biological activities. Thus, the claimed drugs do not have both a common structure and a "common property or activity" as would be required to show that the inventions are "of a similar nature."

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)-272-0735.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

/Carla Myers/
Primary Examiner, Art Unit 1634